REVISION 01
OPI: S&T/MD

UNIDENTIFIABLE MICROBIAL INHIBITION

I. PURPOSE

This directive describes FSIS policy and organizational responsibilities when unidentifiable microbial inhibition is detected during laboratory analysis of meat and poultry tissues for antibiotic residues. The data reported are reviewed periodically to determine the need for new compound identification tests.

II. CANCELLATION

FSIS Directive 10,012.1, dated 11/20/85

III. REASONS FOR REISSUANCE

This directive has been rewritten in its entirety. Many of the program names and form numbers have changed. In addition, Agency policy and responsibilities have been clarified.

IV. REFERENCES

MPI Regulations, Sections 309, 318, and 381

V. ABBREVIATIONS AND FORMS

MD	Microbiology Division
MIC	Microbiologist in Charge
S&T	Science and Technology
SM	Supervisory Microbiologist
TSL	Technical Support Laboratory
UMI	Unidentifiable Microbial Inhibition
210	Reporting Code for UMI

FSIS Form 10,000-2, Laboratory Report, dated 4/92
FSIS Form 10,530-1, Monitoring Residue Program, dated 12/87
FSIS Form 9770-2, Import Residue Program, dated 2/91

VI. DEFINITION

Unidentifiable Microbial Inhibition. Antimicrobial activity in tissue that cannot be attributed to a specific compound.

VII. POLICY

A. FSIS laboratories will report instances when a UMI is found in an official analysis.

B. All UMI data from such reports will be periodically reviewed to determine the need for new compound identification tests.

C. When new compound tests are needed, appropriate identification tests will be developed or procured.

D. After review by the MD, the new tests will be implemented at all FSIS laboratories to reduce the incidence of UMIs.

VIII. PROCEDURES/RESPONSIBILITIES

This section describes the procedures for determining when a UMI exists; identifies responsibilities; describes necessary UMI reporting within the Agency; and provides for a process that will lead to better identification of compounds causing microbial inhibition.

A. The microbiologist/technician at an FSIS laboratory will identify and report any UMI found while analyzing tissue samples for antibiotic residues as follows:

1. Follow instructions for established analytical procedures supplemented by instructions issued by the Director, MD, with concurrence of the Assistant Deputy Administrators, S&T.

2. Exhaust possibilities for identifying a specific antibiotic by use of appropriate FSIS microbiological and immunological tests.

3. Initially, report a UMI on the appropriate laboratory report form. Then, after additional findings are made, prepare or update any report(s) as currently required under standard procedures.

4. Send a tissue sample and FSIS Form 10,000-2, FSIS Form 10,530-1, or FSIS Form 9770-2 with the report of the preliminary UMI finding to the Chemistry Section of the TSL for possible further testing. Update the report(s) as required based on any subsequent findings from other laboratories.

B. The MIC of the TSL or the SM of the Antibiotic Section will review the UMI report and concur on the microbiologist/technician's findings, if appropriate, and will:

1. Determine from chemistry laboratory reports whether additional chemical or other testing is warranted, whether further testing has been completed, and whether results of tests made in the TSL justify or resolve the initial UMI determination.

2. Submit additional tissue samples in response to any written or oral notification made by the SM, TSL, or chemistry laboratory that more samples are needed for additional tests.

3. Record and report according to standard procedure on any specific compound(s) identified as inhibiting microbial growth before the tissue sample was exhausted and became "inadequate."

4. Record and report on appropriate forms final results of all tests carried out by the chemistry laboratory.

5. Enter any data generated by the laboratory under the MIC or the SM into the Laboratory Sample Flow System, using standard operating procedures. The report quantitation code "----" will be entered as "9999."

NOTE: Results of any prior or subsequent testing by another laboratory, such as another TSL or a chemistry laboratory, will be entered by that laboratory.

6. Provide for data evaluation. On a weekly basis, the MIC or the SM at each laboratory will send copies of all final UMI case reports along with the corresponding in-house microbial bioassay result forms, immunoassay result forms, and all available chemical analysis result forms to the Director, MD, for staff review and evaluation. These copies of UMI cases are those reported out for the prior week.

C. The Chemistry Section of the TSL will, when requested, test a tissue sample submitted by the Microbiology Section where a UMI response was initially identified and:

1. Carry out any further testing on a sample that has been reported as an apparent UMI by the Microbiology Section to determine the validity of reporting the result as a UMI.

2. Report to the MIC or SM who submitted the tissue sample, according to standard procedures, any positive identification of a specific antibiotic so that the occurrence of the inhibition is not reported as a UMI.

3. Report to the MIC or SM when the tissue sample is insufficient for completion of all available tests necessary for identifying the substance causing the antimicrobial response. Inability of the laboratory to carry out all available applicable tests because of an "insufficient tissue sample" does not provide the justification for declaring a finding of "UMI."

a. Report to the MIC or SM with respect to tests not completed with the notation on the form, "Insufficient sample available to complete identification of antimicrobial response."

b. Request that the MIC or SM submit an adequate tissue sample for completion of tests.

4. Discard an "insufficient" tissue sample at the point when no further tests can be made. Continue with tests when a new tissue sample is submitted.

5. Enter any data generated by the Chemistry Section into the Laboratory Sample Flow System, using standard operating procedures. The report quantitation code "----" will be entered as "9999."

D. The Microbiology Division will maintain official reports of UMIs and ensure:

1. The validity of the final UMI finding by determining that each tissue sample tested which contains a UMI has been carried through a complete analytical process using all on-line technology available to FSIS laboratories.

2. That a UMI finding is indicated on the currently used FSIS forms by the Code "210," followed by the appropriate tissue code, followed by the appropriate quantitation code that indicates that the UMI is not quantifiable. An example for reporting a UMI detected in a kidney sample is: 210-4 "----."

3. The receipt and logging, on a weekly basis, of the copies of all final UMI case reports that are received.

Note: Each MIC and SM at FSIS laboratories will send in a weekly report accompanied by the in-house analytical result forms that correspond to the cases reported.

E. The Director, MD, will:

1. Provide for staff review and evaluation of all final UMI case reports received from MICs or SMs and reported out for the prior week.

2. Monitor the incidence of reports, periodically evaluate the data, and make recommendations to the FSIS laboratories for further analytical work or test interpretations, as appropriate.

3. Determine the need for and recommend new compound identification tests, with the concurrence of the Assistant Deputy Administrators, S&T.

4. Provide for evaluation of new compound identification tests.

5. Provide for implementation of any satisfactory new compound identification tests at all FSIS laboratories as soon as possible to reduce the incidence of UMIs.

IX. FURTHER GUIDANCE

For further information or answers to questions from laboratory personnel, please call the Director, MD, (202) 205-0212. Questions from inplant inspectors should be directed to the regional residue officers.

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